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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/903,944	07/31/97	CHOU	T 089166/0107

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1638	25

DATE MAILED: 02/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	08/903,944	CHOU ET AL.	
	Examiner	Art Unit	
	David Fox	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45,47-106 and 108-118* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-45,47-106 and 108-118* is/are rejected.

7)☒ Claim(s) *4 and 5* is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1638.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The request filed on 18 November 2000 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/903,944 is acceptable and a CPA has been established. An action on the CPA follows.

The application should be reviewed for errors. Errors appear, for example, in claim 101, which omitted the following phrases (which had been added by the amendment of 13 April 1999):

In parts (b) through (d) of claim 101, after "embryogenic callus", the phrase --containing embyros-- should have been present.

Errors also appear in claim 102, part (b), where "culturing reddish epidermal" should have been replaced with --subculturing embryogenic-- as amended by the amendment of 13 April 1999.

Erros also appear in claim 103, part (g), where "epidermal" should have been replaced with --embryogenic-- per the amendment of 13 April 1999, and in the last line of the claim, where --(l)-- should have appeared before "recovering".

The oath remains objected to for the now incorrect ordering of inventors and for the omission of the complete address for inventor Van Eck, as stated on page 2 of the office action of 11 April 2000.

The amendments and accompanying arguments of 28 November 2000 have obviated the rejection of the claims under 35 USC 112, first paragraph regarding medium components, under 35 USC 102, and under 35 USC 103 over the combination of art with Cheetham et al as the primary reference.

Claims 6-37, 39-45, 47-71, 73-96, 98-100, 102-103, 105-106, 108-112, and new claims 114-115 and 117-118 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to the production of transgenic poinsettia via particle bomdardment, does not reasonably provide enablement for claims broadly drawn to any other method of producing transgenic poinsettia or the plants produced therefrom. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated in the last office action for claims 6-37, 39-45, 47-71, 73-96, 98-100, 102-103, 105-106, and 108-112.

Claims 39-45, 47-72, 99, 103, 106, 109, and 118 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 39 and 103, and dependents, are indefinite in their recitation of "culturing callus produced on medium X on medium Y" as it is confusing whether the callus is being cultured in two media simultaneously, or whether callus originally produced on a first medium is now being

transferred to a second medium. If the latter were intended, the following amendments would obviate this rejection:

In claims 39 and 103, part (b), replace "culturing" with --subculturing-- and replace "in" with --to--.

In claims 39 and 103, parts (e) and (g), replace "culturing" with --subculturing-- and replace the second recitation of "on" with --to--.

Claims 1-3, 97, 101, 104, 113 and 116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Preil et al taken with Nataraja, in light of Lee et al.

Preil (1994) teaches a method for obtaining whole poinsettia plants via somatic embryogenesis, comprising culturing stem segments on a callus induction medium comprising 0.2 mg/L of the cytokinin BAP and 0.2 mg/L of the auxin CPA to form "brownish" callus, followed by subculture to an embryo induction medium comprising 0.1 mg/L of the cytokinin 2iP and a nitrogen source comprising the MS salts which comprise ammonium and nitrate salts, followed by transfer of the embryos to an embryo maturation (or "development") medium comprising 0.05 mg/L of the cytokinin BAP and 3% of the osmotic pressure increasing agent sucrose, followed by subculture to a rooting medium free of cytokinin, wherein whole plants are obtained, wherein suspension culture may be employed, and wherein sieving is employed to recover embryogenic cell clumps and later the embryos themselves (see, e.g., pages 50-53).

Preil et al do not teach the transfer of callus containing the embryos at each step, or the use of casein hydrolysate.

Nataraja teaches the culture of poinsettia zygotic embryos on a medium comprising casein hydrosylate and cytokinin for callus induction, followed by repeated subculture on the medium, wherein embryoids formed which matured into plants (see, e.g., pages 136-137), wherein casein hydrosylate improves callus formation and subsequent plantlet development in poinsettia (see, e.g., page 136, column 1, bottom paragraph and Table 1; and the rest of the article as stated above).

Lee et al teach that the callus obtained by the methods of Preil et al was in fact "reddish epidermal callus" (see, e.g., page 182, column 2, first full paragraph).

It would have been obvious to one of ordinary skill in the art to utilize the callus-mediated method of propagating poinsettia as taught by Preil et al, and to modify that method by incorporating casein hydrolysate as taught by Nataraja, given the expectation that each would have continued to function in its known and expected manner. The callus induced by Preil et al was inherently "reddish epidermal callus" as illustrated by Lee et al, and given the recognition by those of ordinary skill in the art that the terms "reddish" and "brownish" are subjective and overlapping. Choice of culturing isolated somatic embryos or embryogenic callus containing said embryos would have been the optimization of process parameters.

Claims 1-3, 6-8, 11-41, 44-45, 47-106 and 108-118 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miki et al taken with Preil (1994) and Nataraja, in light of Lee et al.

Miki et al teach a particle bombardment technique for plant transformation, wherein a variety of tissues including somatic embryos or embryogenic callus are employed, wherein the

technique has the advantage of being widely applicable to a variety of plant species (see, e.g., pages 77-81), and also teach the advantages of introducing a variety of heterologous structural genes and promoters (see, e.g., pages 67-71).

Miki et al do not teach poinsettia transformation, the use of casein hydrosylate, the claimed sequences of media, or suspension culture of poinsettia.

Preil teaches a multi-step process for the induction of embryogenic callus from poinsettia stem segments and the recovery of whole plants from the somatic embryos, optionally including a suspension culture step, as stated above. Preil also teaches that ABA is beneficial for embryo development and maturation (see, e.g., page 54, paragraph bridging the columns), and suggests the incorporation of poinsettia tissue culture into methods for genetic manipulation of the crop (see, e.g., page 49, column 1, top paragraph).

Nataraja teaches the benefits of casein hydrosylate in inducing poinsettia callus and obtaining whole plants as discussed above.

Lee et al teach that the callus of Preil et al was "reddish epidermal callus" as discussed above.

It would have been obvious to one of ordinary skill in the art to utilize the method of particle bombardment of embryogenic callus for crop improvement as taught by Miki et al, and to modify that method by incorporating the poinsettia embryogenic callus produced by Preil and the medium modifications taught by Preil and Nataraja, as suggested by Preil. The callus initially induced was "reddish epidermal callus" as taught by Lee et al, and given the subjective and

overlapping nature of the terms as discussed above. Choice of culturing isolated somatic embryos or embryogenic callus containing said embryos would have been the optimization of process parameters.

Claims 4, 5, 9, 10, 42 and 43 are deemed free of the prior art, given the failure of the prior art to teach or suggest the use of high concentrations of mannitol for the somatic embryogenesis-mediated propagation of poinsettia.

Claims 4-5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Applicant's arguments filed 28 November 2000, insofar as they pertain to the remaining rejections, have been fully considered but they are not persuasive.

Applicants urge that the enablement rejection regarding non-exemplified means of poinsettia transformation is improper, given the failure of *Agrobacterium rhizogenes* results to be predictive of those using *Agrobacterium tumefaciens,* the inconsistent position taken by the Examiner regarding the enablement rejection and a rejection under 35 USC 103 over Cheetham et al, and the amendment of the claims to delete "electroporation".

The Examiner maintains that Applicants' assertions as to the predictability of *Agrobacterium tumefaciens*-mediated transformation of poinsettia are not deemed probative. See also Applicants' traversal of the Examiner's rejection of the claims under 35 USC 103 as being

obvious over a combination of references involving *Agrobacterium* (see, e.g., pages 12-13 of the amendment of 28 November 2000, which allude to the unpredictability inherent in applying *Agrobacterium* to poinsettia. Regarding the Examiner's allegedly inconsistent position, it is noted that the Examiner has withdrawn the rejection under 35 USC 103 over Cheetham et al in combination with other references.

With regard to electroporation, the Examiner is unable to discern any amendments deleting this term, as alleged by Applicants. Furthermore, some of the method claims do not recite any particular transformation methods, and so read on electroporation as well as polycation-mediated transformation, both of which require wall-less protoplasts, wherein techniques for whole poinsettia regeneration therefrom were not available to the skilled artisan at the time of the invention, as stated in the office action of 7 July 1999, page 3, bottom paragraph).

Applicants urge that the rejection of the claims under 35 USC 103 over a combination of Miki et al and Preil et al is improper, given the failure of Preil et al to suggest the incorporation of poinsettia tissue culture techniques with techniques for genetic manipulation thereof. The Examiner maintains that page 49, column 1, first paragraph provides an explicit statement regarding the advantages of poinsettia tissue culture "for breeding purposes." Furthermore, Miki et al suggests the applicability of microprojectile-mediated transformation to a multitude of plant species recalcitrant to *Agrobacterium*-mediated methods, as discussed above.

Applicants' evidence of unexpected results, namely the genotype-independent obtention of whole, optionally transformed poinsettia plants following micropropagation, relies upon the use of

high levels of a particular osmoticum and high levels of particular nitrogen sources, optionally in combination with microprojectile-mediated transformation. In contrast, the rejected claims are broadly drawn to any osmoticum at any concentration, any nitrogen source or conventional nitrogen sources at conventional concentrations, or any transformation method. See *In re Lindner* and *In re Grasselli* cited in the last office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

February 22, 2001

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638

David T. Fox